

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

| APPLICATION NO.   | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|---|----------------|----------------------|-------------------------|------------------|--|
| 09/815,330  | 03/23/2001     | John A. Zaia         | 1954-333                | 4689             |  |
| ****  | 590 01/15/2003 |                      |                         |                  |  |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C.<br>1425 K STREET, N.W.<br>SUITE 800 |                |                      | EXAMINER                |                  |  |
|   |                |                      | SCHEINER, LAURIE A      |                  |  |
| WASHINGTON, DC 20005  |                | ART UNIT             | PAPER NUMBER            |                  |  |
|   |                |                      | 1648                    | 1/1              |  |
|   |                |                      | DATE MAILED: 01/15/2003 | 14               |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

## Application No. 09/815,330

Applicant(s)

00,0

Examiner

Office Action Summary

Laurie Scheiner

Art Unit 1648

Zaia et al.



| The MAILING DATE of this communication appears on the cover sheet with the correspondence address  |  |   |          |  |  |  |
|--|--|---|----------|--|--|--|
|  | or Reply   |   |          |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the |  |   |          |  |  |  |
| mailing  | date of this communication.  |   |          |  |  |  |
| - If NO p<br>- Failure<br>- Any re   | period for reply specified above is less than thirty (30) days, a reply within the<br>period for reply is specified above, the maximum statutory period will apply and<br>to reply within the set or extended period for reply will, by statute, cause the<br>ply received by the Office later than three months after the mailing date of the<br>patent term adjustment. See 37 CFR 1.704(b). | nd will expire SIX (6)<br>e application to beco | MONTHS f | rom the mailing date of this communication.<br>ONED (35 U.S.C. § 133). |  |  |
| Status   | ,  | •   |          |  |  |  |
| 1) 💢   | Responsive to communication(s) filed on Nov 4, 20  | 02  |          |  |  |  |
| 2a) 🗌  | This action is <b>FINAL</b> . 2b) 💢 This acti  | ion is non-final                                | •        |  |  |  |
| 3) 🗌   | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.   |   |          |  |  |  |
| Disposit   | tion of Claims   |   |          |  |  |  |
| 4) 💢   | Claim(s) <u>1-22</u>   |   |          | is/are pending in the application.                                     |  |  |
| 4  | a) Of the above, claim(s) <u>3-22</u>  |   |          | is/are withdrawn from consideration.                                   |  |  |
| 5) 💢   | Claim(s) 2   |   |          | is/are allowed.  |  |  |
| 6) 💢   | Claim(s) 1   | <del></del> -                                   |          | is/are rejected.   |  |  |
| 7) 🗌   | Claim(s)   |   |          | is/are objected to.  |  |  |
| 8) 🗆   | Claims   | are   | subject  | to restriction and/or election requirement.                            |  |  |
| Applica  | tion Papers  |   |          |  |  |  |
| 9) 🗆   | The specification is objected to by the Examiner.  |   |          |  |  |  |
| 10)□   | The drawing(s) filed on is/are   | a) 🗆 accepte                                    | ed or b) | $\square$ objected to by the Examiner.                                 |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |  |   |          |  |  |  |
| 11)  | The proposed drawing correction filed on   | is  | : a)□ a  | approved b) $\square$ disapproved by the Examiner.                     |  |  |
| If approved, corrected drawings are required in reply to this Office action.   |  |   |          |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.  |  |   |          |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  |  |   |          |  |  |  |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |   |          |  |  |  |
| a) 🗆 All b) 🗀 Some* c) 🗀 None of:  |  |   |          |  |  |  |
| 1.  Certified copies of the priority documents have been received.   |  |   |          |  |  |  |
|  | 2. Certified copies of the priority documents have been received in Application No   |   |          |  |  |  |
|  | 3. Copies of the certified copies of the priority do application from the International Burea  | au (PCT Rule 1                                  | 7.2(a)). | Ç  |  |  |
| _  | ee the attached detailed Office action for a list of the   |   |          |  |  |  |
| 14)∐   | Acknowledgement is made of a claim for domestic  |   |          |  |  |  |
| a) L The translation of the foreign language provisional application has been received.  |  |   |          |  |  |  |
| 15)∟   | Acknowledgement is made of a claim for domestic  | priority under                                  | 35 U.S.  | C. §§ 120 and/or 121.  |  |  |
| Attachm  | ent(s) stice of References Cited (PTO-892)   | 4)  |          | 0.412) Danca Na/a)   |  |  |
| _  | ntice of Preftsperson's Patent Drawing Review (PTO-948)  | _   |          | 0-413) Paper No(s)   |  |  |
| 2) Notice of Draftsperson's Petent Drawing Review (PTO-948)  5) Notice of Informal Petent Application (PTO-152)  3) Information Disclosure Statement(s) (PTO-1449) Peper No(s). and 1:  6) Other:  |  |   |          |  |  |  |
| 74   |  |   |          |  |  |  |

Application/Control Number: 09/815,330 Page 2

Art Unit: 1648

Claims 1-22 are pending in this application. Claims 3-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 1 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The protein (mutant), as claimed, has the same characteristics and utility as that found in nature and therefore does not constitute patentable subject matter. In the absence of the hand of man, the naturally occurring protein (mutant) is considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). See also American Wood v. Fiber Disintegrating Co., 90 US 566 (1974); American Fruit Growers v. Brogdex Co., 283 US 1 (1931); Funk Brother Seed Co. v. Kalo Inoculant Co., 283 US 127 (1984). Amending the claim to recite a purity limitation, such as, "isolated protein", is suggested to obviate this rejection.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 09/815,330

Art Unit: 1648

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Solache et al. (Applicant's citation #72).

Solache et al. clearly teach an isolated mutant cytomegalovirus pp65 capable of eliciting a CTL response against cells infected with cytomegalovirus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242, (703) 305-3014, (703) 872-9306 or (703) 872-9307. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 746-5226.

Laurie Scheiner/LAS January 10, 2003

Page 3